IMMEDIATE EFFECT OF PERCUTANEOUS TRANSVENOUS MITRAL COMMISSUROTOMY ON RIGHT VENTRICULAR FUNCTION

Dissertation Submitted to

THE TAMILNADU DR.M.G.R.MEDICAL UNIVERSITY

in partial fulfillment of the requirements for the award of the degree of

D.M. CARDIOLOGY
BRANCH II – CARDIOLOGY

MADRAS MEDICAL COLLEGE &
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AUGUST 2014

CERTIFICATE

This is to certify that this dissertation titled **"Immediate effect of Percutaneous Transvenous Mitral Commissurotomy on right ventricular function"** submitted by DR. HARIHARAKRISHNAN.R to the faculty of Cardiology, The Tamil Nadu Dr. M.G.R. Medical University, Chennai in partial fulfillment of the requirement for the award of DM degree branch II (Cardiology), is a bonafide research work carried out by him under our direct supervision and guidance. The period of post-graduate study and training was from August 2011 to July 2014.

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DECLARATION

I, **Dr. Hariharakrishnan.R.,** solemnly declare that the dissertation titled **"Immediate effect of Percutaneous Transvenous Mitral Commissurotomy on right ventricular function"** has been prepared by me under the guidance and supervision of **Prof.M.S.Ravi M.D, D.M,** Professor and Head, Department of Cardiology, Madras Medical College and Rajiv Gandhi Government General Hospital, Chennai. This is submitted to The Tamil Nadu Dr. M.G.R. Medical University, Chennai, in partial fulfillment of the rules and regulations for the award of DM degree (branch II) Cardiology.

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ACKNOWLEDGEMENT

At the outset, I wish to thank our Dean **Dr.R.VIMALA, M.D,** and our former Dean **Dr.V. KANAGASABAI, M.D.,** for permitting me to use the facilities of Madras Medical College and Rajiv Gandhi Government General Hospital to conduct this study.

I am indebted to my guide and the Head of Department of Cardiology, **Prof. M.S.RAVI, M.D., D.M** for his constant guidance, advice and encouragement throughout the study and my post graduate period.

I sincerely thank the professors of Cardiology department **Prof K.Meenakshi, Prof. D.Muthukumar, Prof. N.Swaminathan, Prof. G.Ravishankar, Prof. G.Justin Paul** and **Prof.G.Gnanavelu** for their valuable support.

I offer my heartfelt thanks to **Dr. S. Venkatesan M.D, D.M.,** for his valuable advice and support throughout the study.

I offer my heartfelt thanks to the Assistant Professors of the department of Cardiology Dr. G.Palanisamy, Dr.Moorthy, Dr.G.Prathap Kumar, Dr.C.Elangovan, Dr.Rajasekar Ramesh,

Dr.S.Murugan, Dr.G.Manohar, Dr.Elamaran, Dr.Arumugam, Dr.Saravana Babu and Dr.Balaji Pandian for their constant encouragement, timely help and critical suggestions throughout the study.

My patients, who form the most integral part of the work, were always kind and cooperative. I pray for their speedy recovery and place this study as a tribute to them.

My family, friends and fellow post graduates have stood by me during my times of need. Their help and support have been invaluable to the study.

Above all I thank the Lord Almighty for His kindness and benevolence without which this study would not have materialized.

CONTENTS

ABBREVIATIONS

ET	: Ejection Time
IVCT	: Iso Volumic Contraction Time
IVRT	: Iso Volumic Relaxation Time
MPI	: Myocardial Performance Index
MRI	: Magnetic Resonance Imaging
MVO	: Mitral Valve Orifice
PW	: Pulse Wave
RV-MPI	: Right Ventricle- Myocardial Performance Index
RVOT	: Right Ventricular Outflow Tract
RVOT FS	: Right Ventricular Outflow Tract Fractional Shortening
RVSP	: Right Ventricular Systolic Pressure
SPAP	: Systolic Pulmonary Artery Pressure
TR	: Tricuspid Regurgitation
TRPG	: Tricuspid Regurgitation Peak Gradient

INTRODUCTION

1. INTRODUCTION

Rheumatic heart disease (RHD) is a late sequel to acute rheumatic fever, which in turn is an autoimmune reaction to infection by group A beta haemolytic streptococcal infection. Although the incidence has decreased over the past several years, rheumatic heart disease still remains a major cardiovascular problem in developing countries like India. An approximate 3-10% of patients with acute rheumatic fever develop RHD, although the exact incidence in India remains a mystery since acute rheumatic fever is an underreported condition. The most common valvular lesion in RHD is isolated mitral stenosis (MS), which occurs in approximately 40% of patients. RHD is also the commonest cause of isolated mitral stenosis.

There are several pathophysiological implications in rheumatic mitral stenosis. The natural course of rheumatic mitral stenosis is unpredictable, since many patients have a latent asymptomatic period before the onset of symptoms which is highly variable. As the severity of the stenosis increases, there is an obstructive physiology across the mitral valve, the major progressive event being increased pulmonary artery pressure and subsequently progressive right ventricular dysfunction. The right ventricular dysfunction in such patients may result directly from myocardial damage due to the rheumatic

inflammatory process or from secondary hemodynamic changes occurring across the pulmonary vasculature leading to a pressure overloaded right ventricle. The severity of right ventricular function is an important determinant of the onset of symptoms, timing of intervention and the long term outcome of any interventional procedure.

Approximately 40 years ago, the efficacy of surgical mitral commissurotomy was demonstrated by Harken and Bailey. Until the advent of percutaneous transvenous mitral commissurotomy (PTMC), open or closed surgical mitral commissurotomy and mitral valve replacement were the only major options available for the management of mitral stenosis. PTMC is now widely used as the preferred procedure in mitral stenosis in view of its comparatively favourable efficacy and safety profile. The use of PTMC has dramatically changed the outcome of mitral stenosis in the past few years due to immediate favourable alterations in the hemodynamics of the various cardiac chambers. Several studies have shown an immediate and long term improvement in cardiac hemodynamics and right ventricular function after PTMC. Assessment of right ventricular function with echocardiography can be challenging due to its known geometric complexity. This present study was undertaken to assess right ventricular changes immediately after PTMC with simple echocardiographic parameters.

AIM OF THE STUDY

2. AIMS AND OBJECTIVES

1. To analyse the effect of PTMC on various echocardiographic parameters of left and right ventricular function

2. To compare the various echocardiographic parameters of right ventricular function before and after PTMC.

REVIEW OF LITERATURE

3. REVIEW OF LITERATURE

3.1. RHEUMATIC HEART DISEASE: MAGNITUDE AND IMPACT OF THE PROBLEM

Rheumatic fever (RF) and subsequent rheumatic heart disease (RHD) is still a cause for major cardiovascular morbidity, more so in developing countries. There has been a change in the clinical and epidemiological pattern of rheumatic fever in the recent years, with more number of subclinical cases diagnosed by simple echocardiographic methods, suggesting that the Jones criteria may be deemed inadequate for a clinical diagnosis. The mystery concerning the pathogenesis and the susceptibility still remains, as is the area concerning primary prophylaxis. Management of rheumatic heart disease remains the same with the addition of PTMC into the scenario, with better outcomes in the last few years.

There has also been a change in the reported incidence of RHD and RF over the past years. [1] Between 1948 and 1965, a population study revealed that amongst the hospital admissions for cardiovascular diseases, about 20-50% of them were due to RHD. This percentage has definitely reduced and stabilised in the last few decades, including a

possibility of a bias due to an increase in coronary artery disease. A recent Indian Council of Medical Research (ICMR) study (between 2000 and 2010) in 10 different, mostly urban locations of the country found the prevalence to range from 0.2 to 1.1/1000 for RHD and 0.0007 to 0.2 /1000 for RF.[2] The prevalence of RHD in school surveys in various studies ranged from 0.67-2.1/1000. With this overall prevalence, there are an estimated 2-2.5 million people with RHD in India. The following table shows the estimated prevalence of RHD in three major school surveys conducted over the past three decades.

Table 1: Prevalence of Rheumatic heart disease in India

	Age group (years)	Number	Prevalence/1000
Roy [3]	5-30	4847	2.2
Mathur [4]	5-30	7953	1.8
Berry [5]	5-30	19768	1.87
	All ages	33361	1.55

The global burden of RF/RHD is somewhat similar to that of the Indian scenario when the developed economies are excluded. Various population studies have shown an estimated 16-20 million people with RHD (all ages included), with the Asian burden being 11-16

million (all ages). [6][7] Similar global estimates for RF are placed at around 336,000 new cases per year. This did not include the subclinical cases of RF.

Without proper prophylaxis or treatment, approximately 50-80% of patients with RHD progress to congestive heart failure within 20 years, requiring medical or surgical management.

3.2. PATHOPHYSIOLOGY OF RHEUMATIC MITRAL STENOSIS

Before the advent of Jones criteria, the diagnosis of rheumatic fever was chaotic, with no proper treatment or prophylaxis available. This has stabilized to an extent over the past few decades, but with a new surge of patients with subclinical carditis requiring a mandatory echocardiogram for diagnosis, thus questioning the validity of the Jones criteria in present day scenario.

The basic pathology in rheumatic mitral stenosis is commissural fusion with a progressive fibrosis and thickening of leaflets. Stenosis takes about ten years to develop on an average. Most of the symptoms are due to the increase in left atrial pressure with resultant retrograde

events in the pulmonary circulation. The hemodynamic changes in mitral stenosis can be summarised as follows:

1. Increase in left atrial pressure due to mitral valve narrowing

2. Retrograde transmission of left atrial pressure with resultant pulmonary venous congestion, pulmonary oedema and development of pulmonary symptoms due to bronchial vein congestion.

3. Progressive increase in pulmonary arterial pressure

4. Redistribution of blood flow to the upper lobes due to high left atrial pressure and high hydrostatic pressure in the lower lobe vessels.

5. Eventual pressure overload of the right ventricle leading to right ventricular failure.

6. The left ventricular function usually remains normal till end stage cardiac failure sets in. [8]

3.3 STANDARD MANAGEMENT OF RHEUMATIC MITRAL STENOSIS

3.3.1 Echocardiographic assessment in mitral stenosis

Echocardiography plays an important role in deciding the mode of treatment, in selecting the appropriate candidates for PTMC and in

determining the success of an interventional procedure. The following table shows the parameters required to be documented in any case of mitral stenosis.

Table 2: Echocardiographic assessment in a patient with mitral stenosis

	Echo view	Mode	Parameter
1	PLAX	2-D	Wilkins score
2	PLAX	M Mode	Mitral valve mobility and excursion
3	PLAX	CF Doppler	Quantification of MR
4	A4C	CW Doppler	Pulmonary artery systolic pressure
5	PSAX MV level	2-D	Mitral valve area by planimetry
6	PSAX PM level	2-D	Wilkins score, commissural calcification score
7	A4C	CF Doppler	Presence of MR
8	A4C	2-D	Wilkins score
9	A4C	CW Doppler	Mean gradient
10	A4C	CW Doppler	Pressure half time and mitral valve area
11	A2C/3C	2-D	Wilkins score
12	Other considerations		LA size, RV size and function, TOE, other valves, stress echo (if needed)

Abbreviations: A2C: apical 2 chamber; A3C: apical 3 chamber; A4C: apical 4 chamber; CF: colour flow; CW: continuous wave; LA: left atrium; MV mitral valve; MR: mitral regurgitation; PLAX: parasternal long axis; PSAX: parasternal short axis view; PM: papillary muscle; RV: right ventricle; TOE: transoesophageal echocardiography;

The management of mitral stenosis can be classified as symptomatic and definitive. Symptomatic treatment forms an integral backbone of therapy prior to planning an interventional or surgical procedure. Components of medical management include:

1. Treatment of cardiac failure

2. Treatment of arrhythmia –atrial fibrillation

3. Treatment of pulmonary oedema

4. Prophylaxis/treatment of infective endocarditis

5. Secondary prophylaxis for rheumatic fever.

Intervention is currently indicated in patients with clinically significant MS (<1.5 cm2) and in symptomatic patients. Several factors influence the type and timing of intervention including valve anatomy, functional class, comorbidities and physician expertise.

Interventional methods include PTMC, surgical commissurotomy (open or closed) and mitral valve replacement. The following table summarises the indications for all the types of intervention. [8]

Table 3: Methods available for non medical management of mitral stenosis

	Indications
PTMC Closed mitral commissurotomy (CMC)	1.Significant symptoms class II-IV 2.Moderate to severe mitral stenosis 3.Favourable valve morphology
Open mitral valvotomy (OMV)	1. Moderate to severe symptomatic MS 2. Failure of PTMC 3. Associated mild to moderate MR, 4. LA thrombus. 5. Calcified valve
Mitral valve replacement (MVR)	1. Moderate to Severe symptomatic MS when PTMC is unavailable or contraindicated 2. Moderate to Severe symptomatic MS when valve morphology not suitable for PTMC 3. Moderate to Severe symptomatic MS associated with moderate to Severe symptomatic MR

3.4. PTMC

The advent of coronary angioplasty made way for the introduction of balloon techniques in valvular heart disease also. It is a simplified procedure which obviates the need for general anaesthesia, extracorporeal circulation and thoracotomy, when compared with its predecessors. It has now widely become the procedure of choice in mitral stenosis wherever indicated in view of the above advantages. [9] The mechanism by which the mitral valve area increases after PTMC is similar to surgical commissurotomy, that being commissural splitting and this has been proven by in vitro mitral valve studies.[10] Both the calcified and uncalcified mitral commissures are split during the procedure and this contributes to the success of the procedure. The major techniques used are the double balloon technique and the Inoue technique. Until recently, the double balloon technique (initially described by Al Zaibag) was the most successfully used technique, with greater than 100% increase in mitral valve area achieved, that was sustained for over a period of two years. The main disadvantages with the procedure are its technical difficulty and the need for double punctures. This was soon replaced by the Inoue technique, which was technically easier than the double balloon technique with similar

success rates. [11][12] The advantages of the single balloon technique include a shorter procedure time and lesser incidence of left ventricular perforation.

Currently available single balloon catheters include the double lumen Accura balloon and the triple lumen Inoue balloon. Both are made from polyvinyl chloride with a latex balloon at the distal end. The main advantage of Accura balloon over the Inoue balloon is that there is no seepage of blood between the two layers of the balloon. The disadvantage is that there is no provision for prevention of deflation failure.

Factors deciding the size of the balloon include height of the patient, condition of the MV and age of the patient. According to Hung's formula, the size of the balloon is derived from the height of the patients and is most commonly used in clinical practice. The formula is as follows

$$\text{Size of the balloon} = \frac{\text{height in cm (rounded to nearest 10)}}{10} + 10$$

In patients with calcified valve or subvalvular disease, the size of the balloon catheter is one size smaller than the reference size. In older

patients or patients at risk of developing severe MR, smaller size balloon should be used.

3.4.1. Indications for PTMC: [8]

PTMC is indicated in the following scenarios:

1. Patients with symptomatic moderate to severe MS in the absence of LA thrombus and not more than mild MR:
2. Symptomatic (NYHA functional class II, - IV) with valve morphology favourable for PTMC
3. Asymptomatic patients who have pulmonary hypertension [pulmonary artery systolic pressure > 50 mm Hg at rest or > 60 mm Hg with exercise]
4. Symptomatic patients who are either not candidates for surgery or are at high risk for surgery.

Expanding indications include the following:

1. Mitral Restenosis
2. Mitral Stenosis with LA Clot [type Ia, Ib & IIa]
3. Moderate Mitral Regurgitation (Central Jets)

4. Hybrid Therapy - AR, AS, CABG

5. Lutembacher's syndrome

3.4.2 Contraindications for PTMC:

1. Left atrial body clot

2. Grade 2 or more MR

3. Bicommissural calcification

4. Lack of expertise

5. Severe associated aortic valve disease

6. Associated coronary artery disease requiring bypass grafting.

3.4.3 Outcomes of PTMC

Standard definition of a successful PTMC includes the following:

1. An increase in mitral valve area of >50% from baseline (or)

2. Final valve area of >1.5cm^2 (and)

3. Absence of >Sellers Grade 2 MR

The effects of PTMC can be classified as immediate and long term.

3.4.4. Immediate results:

In the majority of the patients a pronounced hemodynamic and clinical improvement is obtained immediately. The most important immediate clinical effect is an improvement in exertional dyspnoea. In a study by Tanabe *et al*, it was observed that this improvement was not accompanied by an increase in lung compliance. The authors proposed that a decrease in excessive ventilation due to a decrease in physiological dead space resulting from hemodynamic improvement partly contributes to the early relief of symptoms after PTMC. [13] The hemodynamic and echocardiographic changes can be summarised as follows:

Table 4: Changes occurring after PTMC

<table>
<tr><th colspan="2">Hemodynamic changes</th><th colspan="2">Echocardiographic changes</th></tr>
<tr><th>Increase</th><th>Decrease</th><th>Increase</th><th>Decrease</th></tr>
<tr><td>Mitral valve area</td><td>Trans mitral gradient</td><td rowspan="4">Mitral valve area</td><td>Trans mitral gradient</td></tr>
<tr><td rowspan="3">Cardiac output</td><td>Mean left atrial pressure</td><td>LA size</td></tr>
<tr><td>Pulmonary artery pressure</td><td rowspan="3">TRPG</td></tr>
<tr><td>Pulmonary vascular resistance (progressive decrease)</td></tr>
</table>

A study of 108 patients by Al-Khalifa *et al* in Sudan showed optimal results in 91.6 % of patients. There was a drop in left atrial mean pressure 32 mmHg to 12 mmHg and left atrial to left ventricular (LV) gradient from an average of 25 to 5 mmHg. Mean mitral valve area increased from 0.86 cm2 to 1.9 cm2 ($p<0.001$) and pulmonary artery (PA) pressure dropped from 71 to 40 mmHg ($p<0.01$). [14] In another study by Salarifar *et al*, it was observed that mitral annular calcification independently had a negative effect on the immediate results of PTMC. [15] In a prospective study by Nobuyoshi *et al*, 106 consecutive patients undergoing PTMC were studied. The authors concluded that a successful PTMC was achieved in 97 patients. There was an immediate decrease in mean LA pressure, mean mitral diastolic pressure gradient and mean mitral valve area.[16] Hildick Smith *et al* studied 106 patients with unfavourable features and observed that 61% of patients had immediate successful PTMC.[17]

Factors influencing the immediate outcome of PTMC

Increase in mitral valve area after PTMC is inversely related to the echocardiographic score. Balloon size directly affects the immediate outcome of PTMC whereas old age, calcification, valvular thickening, subvalvular fibrosis, atrial fibrillation, mitral regurgitation before the

procedure and NYHA class before the procedure inversely affect the outcome of PTMC. Taufiqur Rahman *et al* concluded that patients with atrial fibrillation had a much poorer outcome than patients without atrial fibrillation, although it was not an independent predictor of immediate outcome. Ferrolino *et al* concluded that the Wilkins scoring system was the best predictor of the immediate outcome of PTMC.[18] Ajaz Ahmad *et al* observed that patients with echo score of < 8 have a better outcome and fewer complications compared to those with echo score > 8.[19]

3.4.5. Long-term outcomes of PTMC and the determinants of its success:

The benefit obtained with PTMC in the long run is an ongoing one with increasing clinical and hemodynamic improvement over the first few years. The major events in the long run include restenosis, death, symptomatic deterioration, need for a repeat PTMC and the need for a mitral valve replacement. Restenosis rates vary from 2.4% to 50% in follow-up studies ranging from 2 to 5 years in duration. However, there is a wide difference in the definition of restenosis and the method of assessment so the actual incidence has not been exactly determined. The incidence of adverse events is variable and is associated with different risk factors in various studies.

In a study by Fawzy *et al*, restenosis occurred in 17.6 % of patients and the incidence was lesser in patients with a low echo score. Independent predictors of event free survival (as defined by the appearance of NYHA class III or IV symptoms, death, repeat PTMC or MVR) were mitral echo score and age. This study had a follow up of up to 13 years after PTMC.[20] In the study by Hildick Smith *et al*, event free survival was 96%, 82% and 56% at 1, 3 and 6 years. Freedom from restenosis was 98%, 92% and 75% at 1, 3 and 6 years. Independent predictors of event free survival in this study were male gender, absence of comorbidities, low echocardiographic score and smaller left atrial diameter.[17] Kwan Song *et al* compared the long term outcomes of patients undergoing PTMC and mitral valve replacement. They observed that mitral valve replacement was better in patients with a higher echocardiographic score and atrial fibrillation, whereas those patients without atrial fibrillation and echo score < 8 did not show any difference.[21] Hung *et al* observed that the event free survival rates were more in patients with non calcified pliable valves as compared to those with calcified valves or those with subvalvular fusion (100% versus 76% at 30 months).[22] Similar results were obtained in the study by Pan *et al* (event free survival of 85% at 5 years). The best determinants of survival were presence of non calcified valves and absence of atrial

fibrillation.[23] Cohen *et al* observed a five-year event-free survival rate of 51 %.[24] In the study by Post *et al*, a high immediate success rate was obtained in patients even with severe disease but the eventual long term cardiovascular outcome was not favourable. Hence the authors recommended surgical correction in such patients. [25] Wilkins *et al* concluded in their study that the echocardiographic score was the sole determinant of the outcome of PTMC.[26] Sutaria *et al* observed in their study that PTMC had an acceptable success rate in older patients with mitral stenosis but surgical correction was the preferred procedure in those patients with severe disease. In this study, echo score was not highly predictive of the outcome. [27] Thus, summarising from various studies, the long term outcome of PTMC may be considered as a function of the following factors:

1. Adequacy of the initial PTMC,

2. Presence of atrial fibrillation, severe symptoms

3. Echocardiographic score prior to the procedure.

3.4.6. Complications of PTMC

The major complications of PTMC can be summarised as follows:-[8] [9] [28]

3.4.6.1. Death: Reasons contributing to mortality in post PTMC scenario include:

1. Cardiac perforation
2. Cardiac tamponade
3. Systemic or cerebrovascular embolisation
4. Severe acute mitral regurgitation
5. Acute right heart failure due to a sudden massive increase in pulmonary hypertension in a severely pressure overloaded right ventricle.

Mortality rates ranged from 0.1-1% in various studies and were comparable to that of surgical commissurotomy, with very minimal mortality rates in experienced hands.

3.4.6.2. Cardiac tamponade: This is a very serious although very rare complication of PTMC with a high mortality rate. It may result from either perforation of the heart as a complication of trans septal catheterization or from ventricular perforation caused by the guide wires or the dilating balloon catheters which may slip towards the apex of the left ventricle during inflation. Reported incidence of cardiac tamponade

is very negligible in various studies and is almost nil in experienced hands.

3.4.6.3. Mitral regurgitation: Mild mitral regurgitation occurs in many patients undergoing PTMC with no significant clinical outcome. Severe mitral regurgitation occurring immediately after the procedure is deemed as failure of PTMC but occurs in a much less percentage of patients. It may be due to the tearing of the mitral leaflets and rupture of chordae or a papillary muscle. Severe mitral regurgitation has been reported to be higher with the Inoue technique compared to double balloon techniques. [29]

3.4.6.4. Atrial septal defect: Left-to-right atrial shunting is a very common echocardiographic finding immediately after transseptal PTMC. Clinically insignificant septal defect has been reported in up to 85% of patients if a sensitive technique is used but this is usually well tolerated with no significant hemodynamic outcome. Several studies have tried to determine the mechanisms and factors predicting a shunt across the septum. Factors predicting a shunt included the following:

a. smaller increase in valve area after valvuloplasty,

b. absence of previous mitral commissurotomy,

c. mitral valve calcification,

d. smaller left atria and

e. low cardiac output. [30][31][32]

The long term clinical concern in these patients is that when they develop a restenosis, it is difficult to identify them early since the shunt effectively decompresses the left atrium and this leads to progressive pulmonary hypertension. The other clinical outcome to be watched for is paradoxical embolisation. Although most shunts are clinically and hemodynamically insignificant, they should be carefully observed over the following years.

3.4.6.5. Embolic events: Embolism may occur due to dislodgment of left atrial thrombus or debris from the mitral valve. The incidence of embolism may be higher in patients with atrial fibrillation with undiagnosed thrombus prior to the procedure. Authors recommend meticulous evaluation for left atrial thrombus with trans-oesophageal echocardiography prior to PTMC to avoid this complication. Gas embolism may also occur as a result of balloon rupture.

3.4.6.6. Vascular complications: Vascular complications are mainly related to the procedure and insertion of sheaths or catheters. Major

injury to the femoral vessels in experienced hands is very less since patients are relatively younger without the presence of generalised vascular disease.

3.4.6.7. Minor complications are mainly the usual complications encountered in ordinary heart catheterization. Infective endocarditis is a rare occurrence.

3.4.6.8. Restenosis: Restenosis rate varies from 10-30% in various studies and is the major long term complication of PTMC. A surgical commissurotomy may be recommended in such subset of patients with a higher incidence of morbidity and mortality. In general a repeat PTMC appears to be safe but with a lower success rate than initial procedure. Patients who benefit maximum from a repeat PTMC include those in sinus rhythm and those with a low echocardiographic score.

3.4.7 Advantages of PTMC over surgery

PTMC is the preferred modality of treatment in isolated mitral stenosis wherever possible especially in higher volume experienced centres. As compared to surgical commissurotomy, PTMC is associated with a lower cost, lesser hospital stay and lesser patient discomfort. Both the procedures are comparable in efficacy in various studies. The

absolute contraindications for a PTMC are severe mitral regurgitation and presence of a left atrial thrombus which should be confirmed with a transoesophageal echocardiography prior to the procedure. Amongst the patients with mitral stenosis undergoing a PTMC, the subsets most likely to benefit are those without atrial fibrillation, those with a low echocardiographic score and those without a significant mitral regurgitation. In presence of adverse factors, surgical commissurotomy may yield better results. A high echo score is not an absolute contraindication to PTMC since such patients still have the advantages over surgical commissurotomy like lower mortality, absence of anticoagulation related events, low risk of infection and resurgery. The other advantages of PTMC are that it is non traumatic, can be safely repeated if necessary without any additional risk, has been shown to be a very effective palliative tool in patients with severe end stage mitral stenosis who refuse to undergo the surgical procedure or with unfavourable valve anatomy, and in those patients with co morbidities that preclude surgery.

A systematic review by Xiang Hu *et al* from Cochrane database, pubmed and EMBASE revealed comparative clinical outcomes after both procedures in terms of operative, late complications and mortality

with a higher incidence of restenosis and new onset mitral regurgitation in those undergoing PTMC. [33] Reyes *et al* did a comparative study and observed that there was a similar immediate success rate in both procedures with comparable restenosis rates. The authors concluded that low cost, elimination of need for a thoracotomy and better hemodynamic results at three years made PTMC a method of choice especially in patients with favourable valve morphology. [34] Similar conclusions were obtained in the randomized study by Ben Farhat *et al*.[35] Meneses *et al* studied the immediate and the long term outcomes of patients undergoing PTMC over a period of ten years. They observed that the procedure was safe and effective in at least two thirds of the patients with a sustained long term outcome, this being much superior to the previously available methods of commissurotomy. [36]

3.5 THE RIGHT VENTRICLE IN MITRAL STENOSIS

The right ventricle plays a very important role in mitral stenosis both in terms of symptomatology and in the management. The right ventricle can be indirectly involved in mitral stenosis either by back pressure from the LA or directly by the rheumatic process. Systematic assessment of right ventricular parameters is not routinely performed in all patients due to several reasons including complex structure of the

right ventricle, need for more sophisticated equipment and dominance of left heart evaluation in such cases. In recent past, more importance is being given to the right ventricle for the fact that it is the dominant structure in mitral stenosis. [8]

3.5.1. Echocardiographic assessment of right ventricular function [37]

The common parameters and echocardiographic views measured for RV functional assessment are shown in table 5.

Table 5: Echocardiographic assessment of RV

Echocardiographic views	Parameters
RV focussed Apical four chamber view	RV and RA size
Subcostal view	IVC dimension
Apical four chamber view PSAX at basal level Apical four chamber view Apical four chamber view Apical four chamber view Apical four chamber view Apical four chamber view Apical four chamber view	RV systolic function RV-MPI, TAPSE, 2D RV FAC, 2D RV EF, 3D RV EF, S' of tricuspid annulus, IVA

Abbreviations: EF: Ejection fraction; FAC: Fractional area change; IVA: Isovolumic myocardial acceleration index; IVC: Inferior vena cava; TAPSE: Tricuspid annular plane systolic excursion

3.5.2 Definition of parameters used for assessment of RV function

1. Fractional Area Change (FAC): It is a measure of RV systolic function which has been shown to correlate well with RV ejection fraction on MRI. It is currently one of the recommended methods of quantitative estimation of RV function. The formula for estimation of FAC is as follows

$$\frac{\text{EDA-ESA}}{\text{ESA}} \times 100$$

Where EDA is RV end diastolic area and ESA is RV end systolic area.

2. 2D RV EF estimation: This is measured using the area length method or disc summation method using the apical four chamber view predominantly. The major disadvantage with the use of this parameter is that the RV volumes are underestimated because of exclusion of RVOT. This parameter is not currently recommended because of heterogeneity

of methods and geometric complexity of the RV. The formula for estimation of RV EF is as follows

$$\frac{\text{EDV-ESV}}{\text{EDV}} \times 100$$

EDV is the end diastolic volume and ESV is the end systolic volume.

3.5.3 Definition of parameters used for hemodynamic assessment:

1. RVSP/SPAP: This is estimated using TR velocity with a simplified Bernoulli equation and combining this value with an estimate of RA pressure. RA pressure is estimated from IVC diameter. In the absence of a gradient across the pulmonary valve or RVOT, SPAP equals RVSP. It is recommended that Doppler sweep speeds of 100mm/sec be used for all tracings. If the signal is weak, it may be enhanced with agitated saline or contrast. Overestimation of spectrum can be avoided by ensuring that only well defined dense spectral profile is measured. This parameter is measured using the following formula

RVSP = $4V^2$ + RA pressure where V is peak TR velocity in m/sec

The cut off value for peak TR velocity is 2.8-2.9 m/sec, whereas the peak gradient is usually less that 35-36 mm Hg. Estimation of RA pressure on the basis of IVC diameter and collapse is shown in the following table.

Table 6: RA pressure versus IVC diameter

RA pressure	**Normal (0-5 mm Hg)**	**Intermediate (5-10 mm Hg)**		**High (>10 mm Hg)**
IVC diameter	<2.1 cm	<2.1 cm	>2.1 cm	>2.1 cm
Collapse with sniff	>50%	<50%	>50%	<50%

2. Non volumetric assessment: RV has superficial circumferential muscle fibers responsible for its inward bellow movement as well as inner longitudinal fibers that result in base apex contraction. Assessment of RV function includes global and regional assessment. Global assessment includes RV-MPI, RV dp/dt, RVEF, RVFAC and IVA. Regional assessment includes Doppler derived systolic annular velocity (S') and TAPSE.

(a) RV dp/dt: This gives the rate of pressure rise in the ventricle and is an index of ventricular contractility. This can be accurately estimated from TR continuous wave Doppler signal. It is load dependent and is

calculated by measuring time required for TR jet to increase in velocity from 1 to 2 m/sec. A value of <400mmHg/sec is considered as abnormal.

(b) RV-MPI: This is also known as the RV Tei index. It gives a global measure of both systolic and diastolic function of the RV. It is basically derived from the following formula:

RV Tei index = ratio of IVCT+IVRT/ET

This parameter can be measured by two methods:

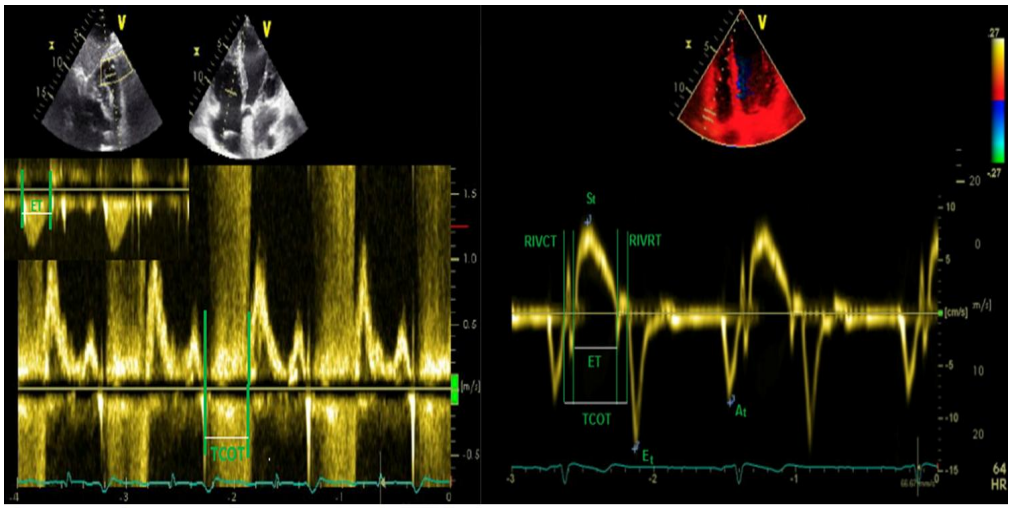
(i)PW method: ET is measured with PW of RVOT and TV closure-opening time is measured from PW Doppler of tricuspid inflow or continuous wave Doppler of TR jet. These measurements are taken from different images.

(ii) Tissue Doppler method: All time intervals are measured from a single beat by pulsing the tricuspid annulus.

A value of >0.40 on PW Doppler and >0.55 on tissue wave Doppler is considered as abnormal. The advantages of measuring this parameter include reproducibility and feasibility and avoidance of geometric assumptions. The disadvantages are that it is load dependent

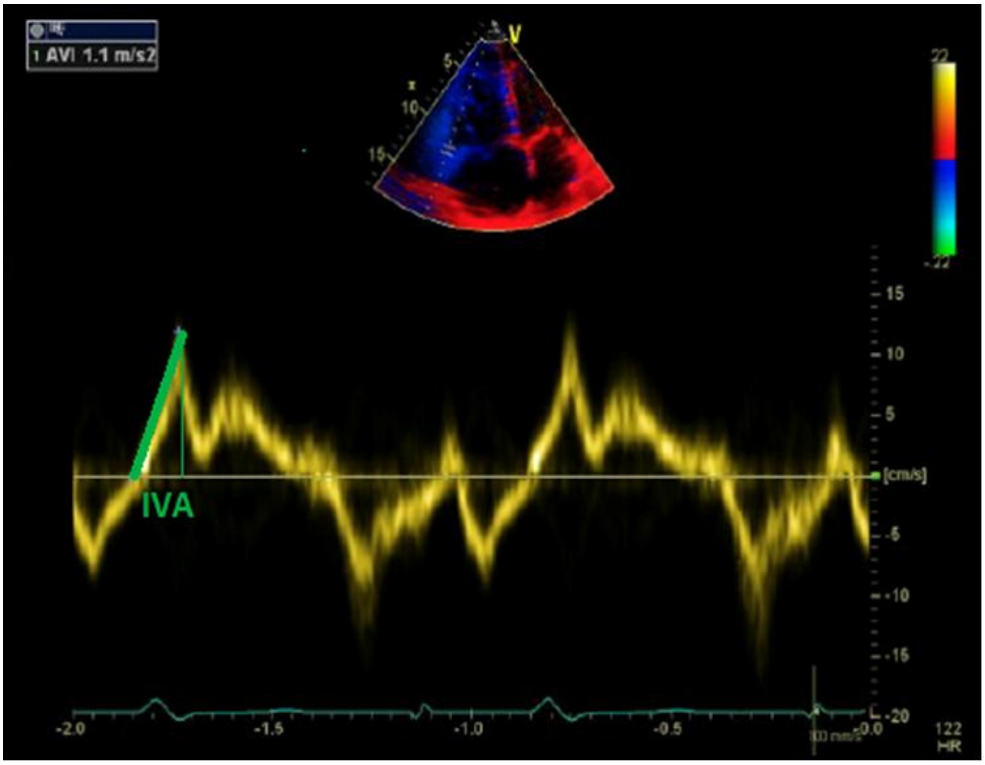
and is also unreliable when measured with different R-R intervals as in atrial fibrillation.

Figure 1: Measurement of RV Tei index



(c): Isovolumic contraction myocardial acceleration index (IVA): This is defined as peak isovolumic myocardial velocity divided by time to peak velocity. It is measured by Doppler tissue imaging at the lateral tricuspid annulus and is considered as the most consistent tissue Doppler index for evaluation of RV function. It has been demonstrated to correlate with severity of illness in conditions affecting RV function like mitral stenosis. It normally lies between 1.5-3 m/sec^2. The advantages include that it measures global RV function and is less load dependent. The disadvantages are that it is age dependent, heart rate dependent and angle dependent.

Figure 2: Measurement of IVA



Regional assessment of RV function:

(i)TAPSE: Tricuspid annular plane systolic excursion: This is a method to measure the distance of systolic excursion of RV annular segment along its longitudinal plane. It is measured in the apical four chamber view and represents the longitudinal function of the RV. The greater the descent of the base in systole, the better the RV systolic function. It is acquired by placing the 'M' mode cursor through the tricuspid annulus. TAPSE correlated strongly with radionuclide angiography in a study by Kaul et al. the normal value is <17 mm. the

advantages include simplicity and reproducibility. The disadvantages are that it is angle dependent and load dependent. It has been recommended that TAPSE should be routinely used as a simple method of estimating RV function.

(ii) Tissue Doppler imaging: This measures the longitudinal velocity of excursion and termed as RV S' or systolic excursion velocity. The PW Doppler sample volume is placed in either the tricuspid annulus or middle of the basal segment of RV free wall. An S' value of <10cm/sec raises the suspicion of abnormal RV function. The advantages are that it is simple and reproducible. The disadvantage is that it is angle dependent.

3.5.4 Evidence for altered RV function in mitral stenosis

In general, it has been considered that correction of mitral stenosis by surgery or repair in any form improves the prognosis of these patients even in the presence of depressed RV function. However, certain studies have shown that in the presence of RV failure or severely depressed RV function, there may be an increase in the perioperative mortality and the long term success of reparative procedures are compromised.[38][39] In a study by Johnston *et al* which compared LV and RV hemodynamics in isolated mitral stenosis, there was an

attenuated response of right ventricular function to exercise whereas the LV hemodynamics remained normal.[40] Sitaram Mittal *et al* performed a Doppler echocardiographic assessment of the right ventricle in asymptomatic patients with mitral stenosis. They observed a significant increase in RV thickness as well as end systolic and end diastolic long axis measurements with a decrease in fractional shortening of these measurements. This suggested an RV dysfunction even in the absence of clinical symptoms. In this study, the authors did not find systolic movement of tricuspid annulus and RV mid cavity short axis dimension sensitive in detecting RV systolic dysfunction. [41]

A study by Yildirimturk *et al* revealed that RV isovolumic acceleration index and RV systolic performance was significantly reduced in patients with mitral stenosis whereas RV myocardial performance index was significantly increases, revealing an impaired RV systolic and diastolic dysfunction. This study was done in patients with mild to moderate mitral stenosis without symptoms thus suggesting that subclinical RV dysfunction was present even in asymptomatic patients. [42] In a study by Mahfouz *et al*, RV dysfunction was identified in all patients with mitral stenosis irrespective of the presence of pulmonary hypertension. Echocardiographic parameters most useful in detecting and prognosticating RV dysfunction were TAPSE and

tricuspid annulus Doppler indices.[43] Sadeghpour *et al* observed that measurements of dP/dt and dP/dt/Pmax, have a good correlation with RV systolic function and functional capacity.[44]

3.5.5 Evidence based medicine: improvement in RV function after PTMC

Recent times have witnessed several studies which have addressed the issue of right ventricular function after PTMC in rheumatic mitral stenosis. Burger *et al* evaluated right ventricular hemodynamics in 19 patients with rheumatic mitral stenosis at rest, after supine bicycle exercise and after valvuloplasty. They found a significant depression of RV function at rest in such patients with further worsening during exercise and with dramatic improvement immediately after PTMC, both at rest and after exercise. This improvement was mainly attributed to an increase in RV stroke volume in this study. [45] In another study done by Mohan *et al*, 25 patients underwent RV functional assessment immediately after PTMC and at one year after PTMC with the help of Doppler method. They found a significant prolongation of right ventricular ejection times with a decrease in isovolumic intervals, which gradually improved over time. In this study, however, the global RV function did not completely reverse. [46]

Drighil *et al* studied RV function indices in 12 consecutive female patients with isolated rheumatic mitral stenosis and observed that there was a significant improvement in infundibular and global RV function after PTMC as evidenced by RVOT fractional shortening and Tei index. However, this study also observed a decrease in RV contractility immediately after PTMC, which the authors partly attributed to the echocardiographic methods.[47] Rahman *et al* measured TAPSE, RV Tei index and systolic myocardial velocities by Doppler studies and concluded that there was a decrease in RV contractility immediately after PTMC but other RV function parameters measured by the RVOTfs and Tei index showed a significant improvement.[48] In a study by Hamdy *et al*, the use of 3D echocardiography in post PTMC scenario revealed a significant improvement of RV systolic dysfunction after 3 months in 38.46% of patients, with significant improvement of dp/dt/EDV 3D index, with a near doubling of this percentage after 6 months.[49] Kundu *et al* assessed the RV function before and after PTMC in 50 patients with mitral stenosis. They observed that there was a significant improvement in global and regional RV function as measured by the RVOT FS% and the RV Tei index which showed a significant increase. This study showed a significant decrease in RV contractility which was measured by the IVA. [50]

MATERIALS AND METHODS

4. MATERIALS AND METHODS

4.1 STUDY DESIGN

The present study was a prospective study based on an interventional procedure conducted in the Department of Cardiology, Madras Medical College and Rajiv Gandhi Government General Hospital for a period of three months starting January 2014. Informed written consent was obtained from all patients prior to the start of the study. Institutional Ethics committee approval was obtained.

4.2 STUDY POPULATION: PATIENT SELECTION

The target number of patients for this study was 30. The criteria for selection of patients were as follows:

Inclusion criteria:

Symptomatic patients with moderate to severe MS with MVO $<1.5\ cm^2$ with valve morphology suitable for PTMC.

Exclusion criteria:

1. MR grade>2
2. Associated LA thrombus

3. Bicommissural calcification.

4. Wilkins score >8

5. Associated significant aortic valve lesions

6. Associated congenital heart defects requiring surgical repair

7. Patients unwilling for the procedure.

4.3 METHODS

All eligible patients underwent a detailed history and clinical examination. Echocardiographic evaluation was done for all patients with Philips HD7XE echocardiographic machine. Various echocardiographic parameters measured were as follows:

1. LV EF%

2. MVO by planimetry and pressure half time

3. Trans mitral mean gradient

4. Trans mitral peak gradient

5. LA size (PLAX)

6. Presence and severity of Mitral regurgitation

7. TAPSE by apical four chamber view

8. TRPG by apical four chamber view

9. RVOT FS% by parasternal short axis view at aortic valve level

10. RV Tei index by pulse Doppler method

11. RV IVA by tissue Doppler method at lateral tricuspid annulus.

All parameters were measured before and within 48 hours after completion of the interventional procedure. The patients' clinical details and echocardiographic values were entered in a proforma and later tabulated for statistical analyses.

4.4 INTERVENTION DETAILS

All eligible patients were administered intravenous pre operative antibiotics 30 minutes before the procedure. Catheterisation was done through both femoral vein and femoral artery on the right side by modified Seldinger technique. Interatrial septal puncture was performed by Hung's technique using the Mullins sheath and Brockenbrough needle. A coiled LA guidewire was introduced through the sheath into the LA. The puncture site was dilated with septal dilator. Accura mitral balloon of corresponding size (decided based on the patients' height

using Hung's formula) was positioned into the LA. The coiled guidewire was replaced with a stylet. By various techniques, mitral valve was crossed with Accura balloon and the balloon was inflated to dilate the orifice. The procedure was done under transthoracic echocardiographic and fluoroscopic guidance. After each dilatation, the mitral valve area by planimetry and severity of MR were assessed. The dilatation was repeated until the MVO increased by $\geq$50% from baseline or development of MR grade >2.

4.5 RESULTS TABULATION AND ANALYSIS METHODS

The results obtained were tabulated in Microsoft Excel format. The results were analysed using the student's t tests for paired data with the help of the SPSS version 20 statistical software. Weighted kappa agreement statistics was used for comparing the various methods of RV function assessment. A 'p' value of <0.05 was considered as significant.

RESULTS AND ANALYSIS

5. RESULTS AND ANALYSIS OF OBSERVED DATA

This prospective intervention based study comprised of 30 consecutive eligible patients who underwent PTMC at the department of Cardiology, Rajiv Gandhi Government General Hospital. The mean age of the patients in this study was 35±6.6 years (range 21-48 years). Forty seven percent of patients were between 30 and 40 years, whereas 33% of patients were between 40 and 50 years. The age distribution of patients is shown in table 7.

Table 7: Age distribution of patients

Age group (years)	No of patients	%
<30	6	20
30-40	14	47
>40	10	33
Total	30	100%

The study predominantly comprised of female patients with 83% being females (n=25) and 17% being males (n=5).

Table 8: Sex distribution

Sex	No of patients	%
Male	5	17
Female	25	83
Total	30	100

The size of the catheter used was 24 in 50% of patients (n=15), 25 in 43% of patients (n=13) and 26 in 7% (n=2)

Table 9: Size of catheter used

Size (mm)	No of patients	%
24	15	50
25	13	43
26	2	7
Total	30	100

Twenty patients (67%) had NYHA class III symptoms prior to the start of the procedure. LV function was normal in all patients at the start of the procedure and remained normal throughout the procedure and thereafter. There was no significant change in LV function after the procedure. Mitral regurgitation was present in 22 patients at baseline with 16 patients having trivial MR and six patients having mild MR. Post procedure MR was observed in 28 patients with 10 patients

having trivial MR, 16 patients with mild MR and two patients with moderate MR. None of the patients had >grade 2 MR as to define an unsuccessful PTMC. The results are shown in tables 10.and 11

Table 10: Mitral regurgitation at baseline and post procedure

Severity	Baseline		Post procedure	
	No of patients	%	No of patients	%
Nil	8	26	2	7
Trivial	16	53	10	33
Mild	6	21	16	53
Moderate	0	0	2	7

Table 11: Pre procedure NYHA Clinical class

Clinical class	No of patients	%
II	20	67
III	10	33

The mean values of various echocardiographic parameters pre and post procedure is shown in table 12. A comparison of values before and after the procedure was done to determine the success of the procedure. All patients had a conversion of clinical class from class

II/III to class I. All patients had a successful PTMC by standard definition using MVO as the gold standard parameter.

Table 12: Echocardiographic parameters: pre procedure versus post procedure

Parameter	Pre procedure	Post procedure	P value
	Mean ± SD	Mean ± SD	
TAPSE (mm)	17 ± 2.3	25 ± 3.3	**<0.001**
RVOT FS (%)	32 ± 4	45 ± 4.6	**<0.001**
RV Tei index	0.35 ± 0.1	0.22 ± 0.1	**<0.001**
IVA (m/sec^2)	2.9 ± 0.7	2.0 ± 0.5	**<0.001**
TRPG (mm Hg)	57 ± 7.7	38 ± 4.2	**<0.001**
MVO (cm^2)	0.8 ± 0.1	1.57 ± 0.12	**<0.001**
LA size (cm)	4.5 ± 0.3	4.1 ± 0.2	**<0.001**
Mean gradient (mm Hg)	15 ± 2.3	6.5 ± 1.2	**<0.001**
Peak gradient (mm Hg)	28 ± 4.36	13 ± 2.6	**<0.001**

The major LV parameters measured were the MVO, LA size, mean gradient and peak gradient. All parameters correlated with a successful PTMC in all patients.

Changes in LV parameters: MVO

All patients had an increase in pre procedure MVO to > 1.5 cm^2. The mean MVO at baseline was 0.8±0.1 cm^2 which increased to 1.57±0.12 cm^2 after the intervention. The increase was statistically significant with a 'p' value of 0.001. Of the 30 patients, 14 patients (46%) had an increase of 50-100%, 13 patients (44%) had an increase of 100-150% and three patients (10%) had an increase of >150% in the MVO as compared to the baseline. The results are shown in table 18.

Table 18: Change in LV parameters: MVO

Percentage increase	**No of patients**	**%**
50-100%	14	46
100-150%	13	44
>150%	3	10
Total	30	100
P value	**<0.001**	

Changes in LV parameters: LA size

The LA size decreased from a mean of 4.5±0.3 cm to 4.1±0.2 cm after the procedure. Forty percent of patients had a decrease of >10% of

LA size immediately after the procedure. The results were statistically significant ($p<0.001$) and are shown in table 19.

Table 19: Change in LV parameters: LA size

Percentage decrease	**No of patients**	**%**
<10%	18	60
>10%	12	40
Total	30	100
P value	**<0.001**	

Changes in LV parameters: Mean and peak gradient

The mean gradient across the MV decreased from a mean of 15$\pm$2.3 mm Hg to 6.5 $\pm$ 1.2 mm Hg. The peak gradient also decreased from 28$\pm$4.3mm Hg to 13$\pm$2.6mm Hg. The decrease in gradient was between 40-60% in about two thirds of patients. The values were statistically significant ($p<0.001$ for mean gradient and $p<0.001$ for peak gradient). The results are shown in tables 20 and 21.

Table 20: Change in LV parameters: mean gradient

Percentage decrease	No of patients	%
<40%	2	6
40-60%	20	66
>60%	8	28
Total	30	100
P value	**<0.001**	

Table 21: Change in LV parameters: peak gradient

Percentage decrease	No of patients	%
<40%	2	6
40-60%	20	66
>60%	8	28
Total	30	100
P value	**<0.001**	

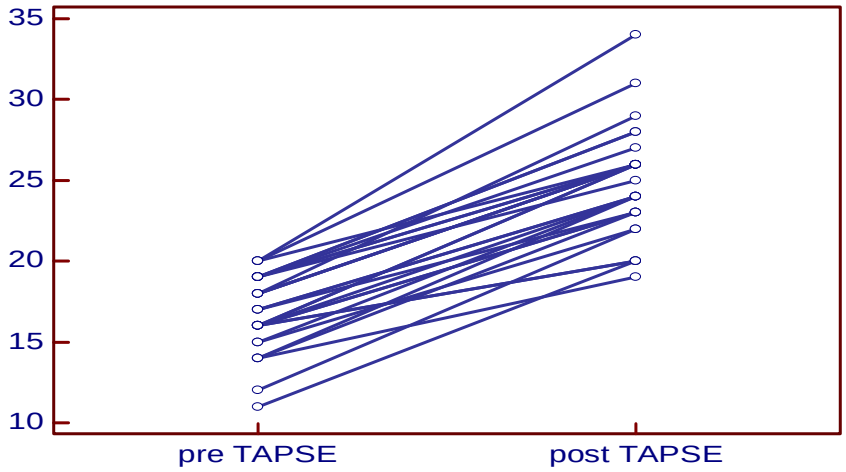
Changes in RV parameters: TAPSE

The mean baseline TAPSE was 17±2.3mm as compared to the post procedural TAPSE of 25±3.3mm.There was a significant increase in post procedural TAPSE with 63% of patients (n=19) having an increase of 30-60%. Eight patients had an increase in TAPSE of >60% from baseline (27%). The difference was statistically significant with a 'p' value of <0.001. The results are shown in table 13.

Table 13: Change in RV parameters post procedure: TAPSE

Percentage increase	**No of patients**	**%**
<30%	3	10
30-60%	19	63
>60%	8	27
Total	30	100
P value	**<0.001**	

Figure 3: Change in TAPSE



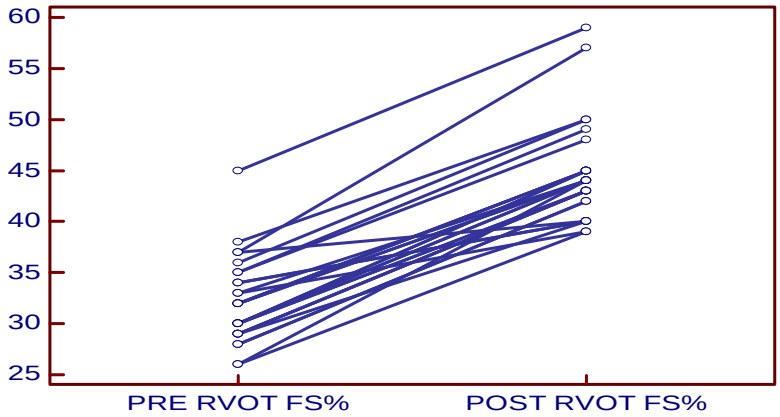
Changes in RV parameters: RVOT FS%:

The mean RVOT FS% increased from 32±4% at baseline to 45±4.6% post procedure. The increase in RVOT FS% was also statistically significant with 83% of patients having an increase in RVOT FS% of 30-60%. Four patients had an increase of <30% from baseline whereas one patient had an increase of >60% from baseline. The 'p' value obtained was <0.001. The results are shown in table 14.

Table 14: Change in RV parameters: RVOT FS%

Percentage increase	**No of patients**	**%**
<30%	4	13
30-60%	25	83
>60%	1	4
Total	30	100
P value	**<0.001**	

Figure 4: Change in RVOT FS%



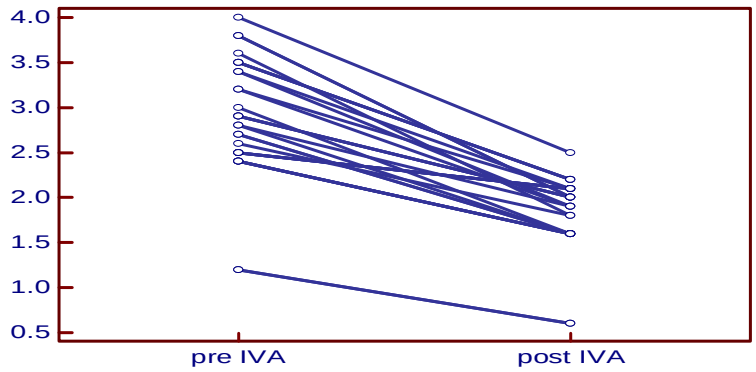
Changes in RV parameters: IVA

A comparison of IVA values pre and post procedure was done. The mean IVA decrease from 2.9±0.7 m/sec^2 to 2.0±0.5 m/sec^2 after the intervention It was observed that all patients had a decrease in IVA after the procedure, of which 30% of patients had a decrease of <20% and 46% of patients had a decrease of 20-40%. Seven patients had a decrease of >40% in IVA. The values were statistically significant with a 'p' value of <0.001. The results are shown in table 15.

Table 15: Change in RV parameters: IVA

Percentage decrease	**No of patients**	**%**
<20%	9	30
20-40%	14	46
>40%	7	24
Total	30	100
P value	**<0.001**	

Figure 5: Change in IVA



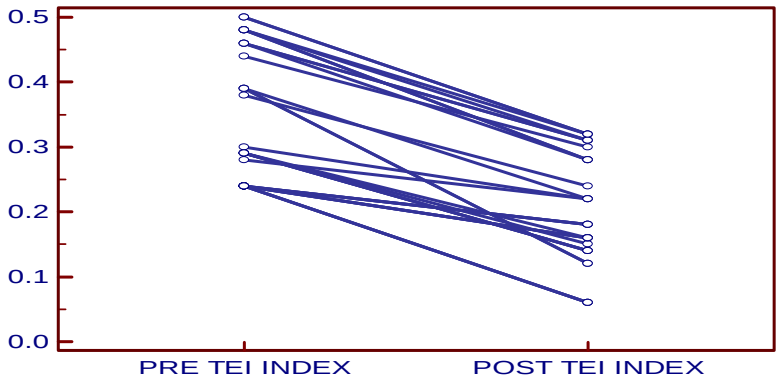
Changes in RV parameters: RV Tei index

The RV Tei index decreased significantly in all patients with 40% of patients having a decrease of <25% and 36% of patients having a decrease of 25-50% from baseline. Seven patients had a decrease of >50% from baseline. The post procedure Tei index was 0.22±0.1 as compared to baseline mean of 0.35±0.1 The results were statistically significant ($p<0.001$) and are shown in table 16.

Table 16: Change in RV parameters: RV Tei index

Percentage decrease	**No of patients**	**%**
<25%	12	40
25-50%	11	36
>50%	7	24
Total	30	100
P value	**<0.001**	

Figure 6: Change in RV Tei index



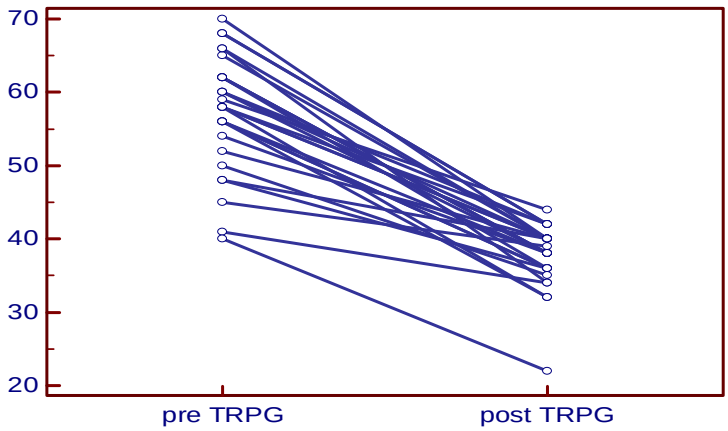
Changes in RV parameters: TRPG

All patients had a decrease in TRPG immediately after the procedure. The TRPG decreased significantly from baseline by 20-40% in 21 patients (70%) and by >40% in six patients (20%). The mean TRPG value decreased from 57±7.7mm Hg to 38±4.2mm Hg. The value was statistically significant with a p value of <0.001. The results are tabulated in table 17.

Table 17: Change in RV parameters: TRPG

Percentage decrease	**No of patients**	**%**
<20%	3	10
20-40%	21	70
>40%	6	20
Total	30	100
P value	**<0.001**	

Figure 7: Change in TRPG



Agreement and Weighted kappa statistics

A comparison of the various RV parameters was done with MVO as the gold standard to determine the better parameter of assessing improvement in RV function immediately after a successful procedure. The statistical method used was the inter observer agreement with weighted kappa statistics. According to the definition of weighted kappa statistics, the agreement was rated as fair, moderate or good. It was observed that the parameter having the best agreement with MVO (successful PTMC) was IVA (κ=0.50) followed by the RV Tei index (κ=0.44). This was better than the agreement scores obtained for the other standard RV parameters like TRPG (κ=0.21, moderate agreement) TAPSE (κ=0.11, fair agreement) and RVOT FS% (κ=0.34, moderate agreement). The results were statistically significant and are shown in table 22.

Table 22: Kappa statistics

Parameter	Kappa value (95% CI)	P value	Agreement
TAPSE	0.11(0.02-0.36)	<0.001	Fair
IVA	0.50(0.25-0.74)	<0.001	Moderate
RV Tei index	0.44(0.22-0.67)	<0.001	Moderate
TRPG	0.21(0.04-0.45)	<0.001	Fair
RVOT FS%	0.34(0.07-0.61)	<0.001	moderate

Post procedural Complications:

Major complications like death, pulmonary oedema and severe MR were not seen in our patients. Local vascular complications in the form of hematoma were seen in two patients which resolved with conservative management. None of the patients had AV fistula or pseudoaneurysm.

DISCUSSION

6. DISCUSSION

Rheumatic heart disease and the long term consequences of mitral stenosis pose a major challenge even today in many developing countries including India. Over the years, there has been a lot of research to understand the enigmatic pathophysiology and timing of intervention in the management. Though there has been good progress, a lot of questions still remain unanswered, thus contributing to the morbidity associated with this condition. In the recent past, the focus has shifted from the left ventricle to the right ventricle and it has been reasonably established that it is the right ventricle which is responsible for the symptoms occurring due to mitral stenosis. Several studies have also established the fact that the functional status of the right ventricle is the key to timely intervention and has often been referred to as the "forgotten chamber".

The best assessment of the functional status of the RV has still not been established due to its complex morphology and heterogeneity of the available methods. Currently the best parameter available for assessment of RV functional status appears to be cardiac MRI, due to the advantages of higher image resolution and ability to calculate three dimensional volumes. However, it involves higher cost, special

equipment and reporting personnel which may not be feasible at all centres. Echocardiography is a useful alternative which is as effective as MRI and is advantageous in terms of wide availability, lesser cost and simplicity of the procedure. It can also be performed in patients who have standard contraindications for MRI. Among the various parameters available for the assessment of RV function, there is no gold standard at present due to lack of standardization. This study was mainly conducted to assess the functional changes occurring in the right ventricle after a PTMC and also to assess the parameter that correlated best with a successful PTMC.

The mean age of patients in our study was 35 ± 6.6 years which is in concordance with world literature. The study population was predominantly female, which is consistent with the epidemiology of the disease. The average age of patients in various studies ranges from 28-36 years with a predominance of patients over the age of 30 years.

The mean mitral valve orifice increased from $0.8 \pm 0.1 cm^2$ before the procedure to 1.57 ± 0.12 cm^2 immediately after the procedure. This is similar to that observed in several studies as shown in the following table.

Table 23: Change in mitral valve area after PTMC

Study	Pre procedure (cm^2)	Post procedure (cm^2)	P value
Hasan Ali[51]	0.9±0.2	2.0±0.4	<0.0001
Drighil [47]	0.91±0.29	1.86±0.43	0.0001
Kundu [50]	0.8±0.1	4.4±0.3	<0.001
Toufiqur Rahman[48]	0.82±0.11	1.75±0.27	<0.01
Sadeghian [52]	1.0±0.2	1.7±0.4	<0.001
Our study	0.8±0.1	1.57±0.12	<0.001

The changes in RV parameters after PTMC obtained in the present study were similar to those observed in other studies. The mean TAPSE in our study was 17±2.3 mm and this is comparable to that seen in a study by Drighil *et al* where it was observed to be 17±2.3 mm. [47] There was a significant increase in the post procedural TAPSE in this study (25±3.3 mm).

Similar results were also observed with RVOTfs%. The baseline RVOTfs% observed in our study was 32±4% which significantly increased to 45±4.6% after the procedure (p<0.001). Drighil *et al*

observed that the RVOTfs% increased from 57±15% to 72±12% after the procedure (p=0.002). [47]Similar values were obtained in the study by Kundu *et al* where the RVOTfs% increased from 54.9±4.6 % to 74.9±4.8% (p<0.001). [50]Rahman *et al* observed an increase of RVOTfs% from 55±13 % to 71±13% (p=0.002). [48]Although the absolute values obtained in the present study are lesser than those observed in other studies, the extent of change is comparable.

The RV Tei index decreased from 0.35±0.1 to 0.22±0.1 in the present study (p<0.001) and is comparable to that obtained in the studies by Drighil *et al* (0.44±0.25 to 0.29±0.17; p=0.02), Kundu *et al* (0.5±0.1 to 0.3±0.1; p<0.001), and Rahman *et al* (0.42±0.02 to 0.27±0.11; p=0.021). [47][50][48]There was a significant decrease in the RV Tei index in the present study which indicates improvement of global RV function. Similar conclusions were obtained in studies done by Drighil *et al* and Kundu *et al.* [47] [50]

The IVA values in our study decrease by about 30% from baseline (2.9±0.7 to 2.0±0.5 m/sec2, p<0.001) and this is comparable with results obtained by Kundu *et al* and Rahman *et al* where a similar decrease was noted (p<0.001 and 0.022 respectively). [48][50] Drighil *et al* found a significant decrease in IVA immediately after PTMC and

concluded that IVA was the most useful parameter in assessing RV function. [47] IVA has been found to be a very valuable marker for assessment of RV function and has shown to have highest correlation with RV systolic function as obtained by MRI in a few studies. It has also been found to have a good correlation with the severity of mitral stenosis and also in predicting RV systolic dysfunction even before the onset of symptoms. In two different studies by Tayyareci *et al,* the IVA proportionately decreased with increasing severity of MS and also had a significant negative correlation with the RV Tei index in patients with MS. The authors concluded in this study that it was a very useful non invasive tool to detect early RV dysfunction. [53][54] The major drawback with use of IVA is the lack of standardization. Its role as the marker for RV function needs to be evaluated in large scale trials for it to become the gold standard.

Agreement statistics in the present study concluded that IVA had highest correlation with the increase in mitral valve area ($\kappa=0.50$; $p<0.001$) closely followed by the RV Tei index ($\kappa=0.44$; $p<0.001$). This agreement was significantly higher than that obtained for the standard parameters such as TRPG and TAPSE. Drighil *et al* concluded that the decrease in IVA after PTMC reflected a decrease in the RV afterload

with subsequent decrease in RV contractile function. They also found that IVA was more sensitive marker of RV function than myocardial systolic velocities because of the reason that myocardial motion disturbances occurred most commonly during the isovolumic phases. They also concluded that since Tei index is sensitive to load, it may be less sensitive in predicting global RV function improvement when compared with IVA which is not load dependent. [47]

Limitations of the study:

1. There were several limitations in this study. There was no control population and hence a comparison of parameters with those of study group was not possible, leading to absence of standardization in this population.

2. The study sample was small, hence it needs to be evaluated whether the results obtained in this study would generalize to other patients groups or not. Clinical trials with larger study populations are needed to assess this.

3. This study evaluated only the immediate effect of PTMC on RV function (within 48 hours). Long term benefits of PTMC

on RV function parameters need to be evaluated in follow up studies to assess the usefulness of the parameters.

4. IVA values have not been standardized using a control population; hence there is a lack of standard reference values. Another disadvantage with using IVA as a marker of RV function is that it is angle dependent and hence there is a possibility of inter-observer and intra-observer variability.

5. All patients in this study had severe mitral stenosis and it remains unclear whether similar results would apply to patients with moderate MS also.

The results of this study need to be validated in larger trials with a larger number of patients. IVA is a newer echocardiographic parameter for assessing the RV global function rather than regional function which is more important in mitral stenosis. However, there is very limited number of studies to assess the usefulness of IVA in MS with no standard reference values. Once the parameter is validated in large scale studies, it will probably become an important marker of RV systolic function.

Currently 3D echocardiography is considered to be one of the better tools to assess RV function and has been found to be as effective as cardiac MRI. The major advantage of 3D echocardiography is the ability to view the complete RV geometry and to measure RVEF and volumes. It may be the method of choice for assessment of RV function in the near future but there are only limited studies available at present.

CONCLUSION

7. CONCLUSIONS

1. There was significant improvement in global and regional right ventricular function immediately after PTMC as measured by the various echocardiographic parameters like TAPSE, RVOT FS%, RV IVA, TRPG and RV Tei index.

2. Right ventricular Isovolumic myocardial acceleration index had highest agreement with the gold standard method of assessing successful PTMC namely MVO, which was closely followed by RV Tei index.

3. Both RV IVA and RV Tei index were effective in assessing RV global function.

4. Further research is needed to assess the validity of these parameters in larger studies and in comparison with cardiac MRI.

APPENDIX

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PROFORMA

Name Height

Age Weight

Sex

Diagnosis

Balloon Size

S No	Method	Parameter	Pre PTMC	Post PTMC
1	**M mode**	TAPSE RVOT FS %		
2	**Continuous Doppler**	TR velocity TR PG(RVSP)		
3	**Pulse wave doppler**	TV closure- opening time Pulmonary ejection time RV Tei index		
4	**Tissue Doppler**	Isovolumic contraction myocardial Acceleration index		
5	**Mitral stenosis**	Clinical class MVO (Planimetry) Mean gradient Peak gradient LV function Mitral Regurgitation LA size		

MASTER CHART

				pre		post		pre	post	pre		post		pre							post						
S NO	AGE	SEX	Balloon size	TAPSE	RVOTfs %	TAPSE	RVOTfs%	TRPG	TRPG	IVA	RV MPI	IVA	RV MPI	NYHA class	MVO	mean gr	peak gr	LV EF(%)	MR	LA size	NYHA class	MVO	mean gr	peak gr	LV EF(%)	MR	LA size
1	42	F	24	20	34	26	40	50	35	2.8	0.28	1.9	0.22	III	1.0	17	28	70	TR	4.4	I	1.6	9	14	70	TR	4.1
2	48	F	24	16	26	20	44	65	40	3.8	0.30	2.0	0.22	III	0.6	14	24	65	NIL	4.6	I	1.6	8	14	67	NIL	4
3	45	F	25	16	34	20	40	48	40	2.9	0.29	2.0	0.15	III	0.7	10	18	70	TR	3.9	I	1.4	6	10	70	TR	3.6
4	26	F	24	20	37	34	40	45	39	2.4	0.24	1.6	0.06	III	1.0	12	20	65	TR	4.4	I	1.7	5	8	65	MI	4
5	41	F	25	11	29	20	43	41	34	3.5	0.29	2.2	0.14	III	0.9	14	24	60	TR	4.4	I	1.6	7	14	60	MI	4.1
6	40	M	25	20	37	31	57	66	34	2.5	0.24	2.1	0.18	III	0.8	19	33	70	NIL	4.6	I	1.6	9	20	70	NIL	4.1
7	42	F	24	12	33	22	39	40	22	2.7	0.24	1.6	0.16	II	1.0	14	28	66	TR	4.6	I	1.5	7	13	66	MI	4.2
8	32	F	25	19	45	26	59	56	32	1.2	0.39	0.6	0.12	II	0.7	13	24	70	TR	4.2	I	1.4	6	13	70	MI	3.9
9	28	F	24	14	33	19	44	60	42	2.4	0.24	1.6	0.06	III	0.7	14	29	65	TR	4.4	I	1.5	6	13	66	MI	4.1
10	34	F	25	18	30	26	45	52	40	3.5	0.29	2.2	0.14	III	0.8	16	33	60	TR	4.8	I	1.6	5	11	62	MI	4.4
11	36	F	24	19	28	25	42	48	36	2.5	0.24	1.4	0.18	III	0.6	12	25	75	MI	4.3	I	1.5	7	14	76	MI	3.9
12	28	M	25	17	32	23	45	59	44	2.5	0.24	2.1	0.16	II	1.0	16	30	70	NIL	4.9	I	1.6	7	12	70	TR	4.3
13	30	F	24	19	38	28	50	58	40	2.7	0.24	1.9	0.16	II	0.9	19	33	72	TR	5.1	I	1.6	8	17	72	MI	4.4
14	34	F	24	18	30	26	45	62	38	1.2	0.39	0.6	0.12	III	0.6	13	26	66	TR	4.2	I	1.4	6	11	68	MI	3.7
15	43	F	25	16	28	24	42	60	40	2.4	0.24	1.6	0.06	III	0.8	16	33	64	TR	4.6	I	1.6	6	13	65	TR	4.1
16	40	F	25	14	32	23	45	56	38	3.8	0.29	2.4	0.14	III	0.7	15	28	63	MI	4.7	I	1.5	7	14	64	MI	4.4
17	37	F	26	15	30	22	43	62	36	2.9	0.24	2.5	0.18	II	0.9	12	26	65	MI	4.9	I	1.7	8	17	65	MO	4.3
18	31	F	24	19	36	26	50	54	38	2.4	0.38	1.9	0.24	III	1.0	14	24	68	MI	4.3	I	1.7	5	9	68	MI	3.9
19	40	F	24	17	30	24	44	58	32	3.5	0.46	2.8	0.31	III	0.8	19	33	70	NIL	5.2	I	1.5	7	12	70	TR	4.5
20	32	M	24	16	29	23	43	66	40	2.5	0.48	2.1	0.28	II	0.6	14	28	72	NIL	4.2	I	1.4	6	11	72	TR	3.8
21	33	F	25	15	32	24	44	68	42	2.8	0.50	2.0	0.32	III	0.7	13	24	74	TR	4.6	I	1.3	5	11	74	MI	4.2
22	27	F	24	19	26	28	39	62	38	3.4	0.44	2.8	0.30	III	1.0	14	29	70	TR	4.4	I	1.7	6	14	70	MI	4.1

S NO	AGE	SEX	Balloon size	pre		post		pre	post	pre		post		pre							post						
				TAPSE	RVOTfs %	TAPSE	RVOTfs%	TRPG	TRPG	IVA	RV MPI	IVA	RV MPI	NYHA class	MVO	mean gr	peak gr	LV EF(%)	MR	LA size	NYHA class	MVO	mean gr	peak gr	LV EF(%)	MR	LA size
23	31	F	25	18	32	26	44	58	40	2.9	0.48	2.0	0.28	II	0.8	16	33	65	MI	4.4	I	1.6	7	12	66	MI	4
24	29	F	25	17	30	24	43	56	36	3.2	0.46	2.6	0.31	III	0.9	13	26	64	TR	4.8	I	1.7	5	11	66	M I	4.4
25	25	F	25	16	35	26	49	70	40	2.6	0.48	1.5	0.32	III	0.6	16	33	68	TR	4.3	I	1.5	6	11	68	TR	3.8
26	38	M	24	14	29	24	43	68	42	4.0	0.29	2.5	0.16	III	0.8	15	28	62	TR	4.2	I	1.6	6	12	64	MI	3.9
27	35	M	24	16	32	23	45	62	38	3.2	0.39	1.9	0.22	II	0.7	12	26	60	NIL	4.4	I	1.5	5	11	62	TR	3.9
28	21	F	25	18	30	29	44	58	42	3.6	0.48	1.8	0.31	II	0.9	14	24	68	MI	4.5	I	1.7	5	9	68	MO	4.1
29	42	F	26	19	35	27	48	56	36	3.4	0.46	2.7	0.28	III	1.0	16	34	66	NIL	4.9	I	1.7	8	15	66	TR	4.4
30	31	F	24	16	29	26	40	60	38	3.0	0.50	1.9	0.32	II	0.9	18	35	65	NIL	4.6	I	1.8	8	17	65	TR	4.1

PATIENT INFORMATION SHEET AND CONSENT FORM

ஆராய்ச்சி தகவல் தாள்

சென்னை அரசு பொது மருத்துவமனைக்கு வரும் ருமெடிக் மைட்ரல் வால்வு அடைப்பு உள்ள நோயாளிகளிடம் புறத்துளை மூலம் மைட்ரல் வால்வை விரிவுபடுத்தும் செய்முறைக்கு முன்னரும் பின்னரும் வலது வென்ட்ரிக்கிலில் உண்டாகும் மாற்றங்களை செவிஉனரா ஒலி இதய கணிப்பு கருவி வாயிலாக ஆராய உள்ளோம் .

நீங்கள் இந்த ஆராய்ச்சியில் பங்கேற்க நாங்கள் விரும்புகிறோம். இந்த ஆராய்ச்சியில் பங்கேற்பதால் தங்களது நோயின் ஆய்வறிக்கையோ அல்லது சிகிச்சையோ பாதிக்கப்படாது என்பதையும் தெரிவித்துக் கொள்கிறோம்.

இந்த ஆராய்ச்சியின் முடிவுகளை அல்லது கருத்துகளை வெளியிடும் போதோ அல்லது ஆராய்ச்சியின் போதோ தங்களது பெயரையோ அல்லது அடையாளங்களையோ வெளியிடமாட்டோம் என்பதையும் தெரிவித்துக் கொள்கிறோம்.

இந்த ஆராய்ச்சியில் பங்கேற்பது தங்களுடைய விருப்பத்தின் பேரில் தான் இருக்கிறது. மேலும் நீங்கள் எந்நேரமும் இந்த ஆராய்ச்சியில் இருந்து பின்வாங்கலாம் என்பதையும் தெரிவித்துக்கொள்கிறோம்.

இந்த சிறப்புப் பரிசோதனைகளின் முடிவுகளை ஆராய்ச்சியின் போதோ அல்லது ஆராய்ச்சியின் முடிவின் போதோ தங்களுக்கு அறிவிப்போம் என்பதையும் தெரிவித்துக்கோள்கிறோம்.

ஆராய்ச்சியாளர் கையொப்பம் பங்கேற்பாளர் கையொப்பம்

தேதி:

சுய ஒப்புதல் படிவம்

<u>ஆய்வு செய்யப்படும் தலைப்பு</u> ருமெடிக் மைட்ரல் வால்வு அடைப்பு உள்ள நோயாளிகளிடம் புறத்துளை மூலம் மைட்ரல் வால்வை விரிவுபடுத்தும் செய்முறைக்கு முன்னரும் பின்னரும் வலது வென்ட்ரிக்கிலில் உண்டாகும் மாற்றங்களை செவிஉணரா ஒலி இதய கணிப்பு கருவி வாயிலாக ஆராய்தல்.

<u>ஆராய்ச்சி நிலையம்</u> : இருதய மருத்துவத் துறை,
இராஜீவ் காந்தி அரசு பொது மருத்துவமன
மற்றும் சென்னை மருத்துவக்கல்லூரி,
சென்னை – 600 003.

பங்கு பெறுபவரின் பெயர் : **உறவு முறை:**

பங்கு பெறுபவரின் எண் :

பங்கு பெறுபவர் இதனை (√) குறிக்கவும்

மேலே குறிப்பிட்டுள்ள மருத்துவ ஆய்வின் விவரங்கள் எனக்கு விளக்கப்பட்டது. என்னுடைய சந்தேகங்களைக் கேட்கவும், அதற்கான தகுந்த விளக்கங்களைப் பெறவும் வாய்ப்பளிக்கப்பட்டது. ☐

நான் இவ்வாய்வில் தன்னிச்சையாகத்தான் பங்கேற்கிறேன். எந்தக் காரணத்தினாலோ எந்தக் கட்டத்திலும் எந்த சட்ட சிக்கலுக்கும் உட்படாமல் நான் இவ்வாய்வில் இருந்து விலகிக் கொள்ளலாம் என்றும் அறிந்து கொண்டேன். ☐

இந்த ஆய்வு சம்மந்தமாகவும், மேலும் இது சார்ந்த ஆய்வு மேற்கொள்ளும்போதும், இந்த ஆய்வில் பங்குபெறும் மருத்துவர் என்னுடைய மருத்துவ அறிக்கைகளைப் பார்ப்பதற்கு என் அனுமதி தேவையில்லை என அறிந்துகொள்கிறேன். நான் ஆய்வில் இருந்து விலகிக் கொண்டாலும் இது பொருந்தும் என அறிகிறேன். ☐

இந்த ஆய்வின் மூலம் கிடைக்கும் தகவல்களையும், பரிசோதனை முடிவுகளையும் மற்றும் சிகிச்சை தொடர்பான தகவல்களையும் மருத்துவர் மேற்கொள்ளும் ஆய்வில் பயன்படுத்திக் கொள்ளவும், அதைப் பிரசுரிக்கவும் என் முழு மனதுடன் சம்மதிக்கிறேன். ☐

இந்த ஆய்வில் பங்கு கொள்ள ஒப்புக்கொள்கிறேன். எனக்குக் கொடுக்கப்பட்ட அறிவுரைகளின் படி நடந்துகொள்வதுடன், இந்த ஆய்வை மேற்கொள்ளும் மருத்துவ அணிக்கு உண்மையுடன் இருப்பேன் என்றும் உறுதியளிக்கிறேன். என் உடல் நலம் பாதிக்கப்பட்டாலோ அல்லது எதிர்பாராத வழக்கத்திற்கு மாறாக நோய்க்குறி தென்பட்டாலோ உடனே அதை மருத்துவ அணியிடம் தெரிவிப்பேன் என உறுதி அளிக்கிறேன். ☐

இந்த ஆய்வில் எனக்கு மருத்துவப் பரிசோதனை, இரத்தப் பரிசோதனை மற்றும் நரம்பு மின் பரிசோதனை செய்து கொள்ள நான் முழு மனதுடன் சம்மதிக்கிறேன். ☐

பங்கேற்பவரின் கையொப்பம் ..... இடம் ..... தேதி .....

கட்டைவிரல் ரேகை:

பங்கேற்பவரின் பெயர் மற்றும் விலாசம் .....

ஆய்வாளரின் கையொப்பம் ..... இடம் ..... தேதி .....

ஆய்வாளரின் பெயர் .....

INSTITUTIONAL ETHICS COMMITTEE

MADRAS MEDICAL COLLEGE, CHENNAI – 600 003.

EC Reg. No. ECR /270/Inst/TN/2013

Telephone No. 044 25305301

Fax 044 25363970

CERTIFICATE OF APPROVAL

To

Dr .R.Hariharakrishnan ,

Post graduate in DM Cardiology,

Department of Cardiology,

Madras Medical College, Chennai 600 003.

Dear Dr. R. Hariharakrishnan ,

The Institutional Ethics Committee of Madras Medical College , reviewed and discussed your application for approval of the proposal IMMEDIATE IMPACT OF PERCUTANEOUS TRANSVENOUS MITRAL COMMISSUROTOMY ON RIGHT VENTRICULAR FUNCTION No. 04022014.

The following members of the Ethical Committee were present in the meeting held on 04.02.2014 conducted at Madras Medical College, Chennai – 3.

1. Dr .G.Sivakumar , MS FICS FAIS Chairperson
2. Prof.B.Kalaiselvi , MD Vice Principal, MMC, Ch3 Member Secretary
3. Prof.Ramadevi ,Director i/c, Institute of Biochemistry Member
4. Prof. Siva Subramanian, Director i/c, Institute of Internal Medicine Member
5. Thiru .S.Govindasamy , BA., BL., Lawyer
6. Tmt .ArnoldSaulina , MA MSW Social Scientist

We approve the proposal to be conducted in its present form.
Sd / Chairman & other Members.

The Institutional Ethics Committee expects to be informed about the progress of the study , and SAE occurring in the course of the study , any changes in the protocol and patients information / informed consent and asks to be provided a copy of the final report.

10/2/14.

Member Secretary , Ethics Committee

MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE
CHENNAI-600 003

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Dissertation Submitted to

THE TAMILNADU DR.M.G.R.MEDICAL UNIVERSITY

in partial fulfillment of the requirements for the award of the degree of

DM (CARDIOLOGY) - Branch II

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